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Patentanmeldung Nr. Patent application No. Demande de brevet n°

01810243.4

PRIORITY DOCUMENT

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For the President of the European Patent Office

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Blatt 2 der Bescheinigung
Sheet 2 of the certificate
Page 2 de l'attestation

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Longitudinal Implant

This invention relates to a longitudinal implant and connecting device wherein said longitudinal implant is fastened to bones on either side of a damaged area through said connecting device.

In some spinal repair situations, the damaged area of the spine is spanned by a slotted plate through which pedicle screws are inserted and fastened to the pedicle bones on either side of a damaged area. This fixes the spatial distance between the pedicle bones and therefore fixes the distance between vertebrae so that the damaged area of the spine can be repaired. In other spinal situations, the damaged area of the spine is spanned by a rod. At least two connectors are slidable along the rod connecting pedicle screws or hooks to the rod. Such a rod and fixation system is disclosed in EP 0 923 908A (Robert Lange).

Spinal repair is often times accomplished with hollow cages in which bone fragments are inserted that will grow to an extent to fuse the upper and lower vertebrae together at the damaged area. By fixing and holding the distance between these vertebrae, the bone in the cages will have time to grow and join the vertebrae together.

It is an objective of this invention to provide an elongated implant and pedicle screw or hook fixation system providing an increased stability.

The implant of the device according to this invention is comprised of a filament composite material and said pedicle screws

or hooks are made of a material harder than said implant. The implant provides a surface that has more friction than a titanium implant. If the implant is a plate having a longitudinal slot, the plate is placed between a nut and an upper surface of a pedicle screw. The plate can be squeezed and locked into position because the squeezing and the increased friction between titanium and the filament composite material. When all members are titanium, the required position is not always available and indentations are often provided along the slot.

Fixation systems manufactured from metals such as titanium alloy and stainless steel confound postoperative radiologic assessments because they are radiopac and can produce artefact.. The use of an implant comprised of a fiber reinforced polymer composite permits better diagnostic assessment of soft tissue and bone by normal radiographic methods.

According to a preferred embodiment of the invention, the fibers are aligned lengthwise, so that compression will not change their strength characteristics to any extent even when compressed. Preferably the fibers or filaments are oriented to resist biomechanical forces.

Other advantages and features of the present invention will be apparent to those skilled in this art reaching the following specification with reference to the accompanying drawings in which:

Fig. 1 is a view of an embodiment of an implant of this invention;

Fig. 2 is a section along line I-I of Figure 1;

Fig. 3 is a section through an embodiment of the implant with a different curvature;

Fig. 4 shows the implant according to Figure 3 connecting two pedicle screws;

Fig. 5 a schematic view of a material block with horizontal fiber and an implant machined from this block;

Fig. 6 a schematic view of a material block with a curvature fiber orientation and an implant machined from this block;

Fig. 7 a side view of a connecting device of this invention;

Fig. 8 a partial section through the connecting device;

Fig. 9 a side view of an implant testing configuration;

Fig. 10 and 11 overall views showing rods or rails connecting two vertebrae of a spinal cord;.

Fig. 12 a perspective view of another embodiment of an impant of this invention and

Fig. 13 a section along line XIII-XIII of figure 12.

Figures 1 and 2 disclose a plate 1 having a longitudinal slot 2 extending along a substantial portion of its length. The plate has a curvature of about 10^0 as shown in Figure 2. Figure 3 discloses a plate 1' which has a curvature of 20^0.

The plates 1 and 1' as well as rods 30 and rails 17 are manufactured from a composite material composed of long filaments or fibers 18 and 19 encapsulated in a matrix 4 as shown in Figure 13. The filaments or fibers 18 and 19 are preferably long carbon filaments and the matrix is preferably a polymer. Preferably the carbon filaments or fibers 18 and 19 are encapsulated in the polymer polyether-ketoneetherketoneketone (PEKEKK). PEKEKK is a known biocompatible polymer. Another possible polymer is polyetheretherketone (PEEK). PEKEKK is preferred to PEEK because of

its greater physical and chemical resistance properties. These characteristics impart greater stability to the plates 1 and 1' rods 30 and rails 17 or other conncecting parts during a long-term implantation.

Figures 4, 7 and 8 disclose a pedical plate fixation systems 5 and 5' comprising a plate 1', two bone screws 6 and two nuts 7. The screws 6 and the nuts 7 are manufactured from steel or medical grade titanium alloy. Bone screws 6 are common in the orthopedic arts. The screws 6 are provided with bone engaging threads 6a and at its other end a screw segment 6b with a conventional thread. The thread 6a flairs outwardly to an enlarged portion 6c. The enlarged portions 6c having a width greater than the width of the slope 2. The screw segment 6b extending outwardly from the enlarged portion 6c and extending through the slot 2. The nut 7 is received by the screw segment 6b, whereby the plate 1' can be grasped between the enlarged portion 6c and the nut 7 to tightly secure the plate 1 by threading the nut 7 toward the enlarged portion 6c.

The embodiment according to Figure 7 is provided with slip washers 20, 21 and 22 having a planar surface 20a, 21a, 22a and a concave or convex surface 20b, 21b, 22b. The planar surfaces 20a and 21a are touching the plate 1' are preferably provided with rips (not shown), which are depressed in the plate 1' and which prevent the screw 6 from moving along the slot 2.

As the carbon-filament composition material of the plate 1 is softer than titanium and at its surface is somewhat rougher than a titanium surface, the plate 1 can be squeezed between the enlarged portion 6c and the nut 7. This prevents the screws 6 from moving along the slot 2 both by depression caused by the squeezing and the enhanced friction there between.

The filaments 3 encapsulated in the polymer matrix 4 are oriented as shown in figures 7 and 8. The plate 1 is machined from a block 8 having a curvature fiber orientation as indicated in Figure 6. The curvature of the fiber lay-up is the same as the curvature of the plate 1 or plate 2. The filaments 3 in the matrix 4 are therefore aligned lengthwise of the slot 2. The Figure 5 shows a block 8' with a parallel curvature lay-up and the in the plate 1'' machined from this block 8' the filaments do not follow the curvature of the plate 1'' and are shorter. With the testing configuration 10 disclosed in Figure 9, tests were conducted using the ASTM provisional standard for spinal implants. This mechanical testing has shown that the strength of the plate 1 and 1' is similar to plates made from stainless steel and titanium. The goal of stabilization has not been sacrified. As material of the plates 1 and 1' is radiolucent, the plates do not interfere with diagnostic methods.

As already mentioned, the implant according to this invention can also be a rod 12 as disclosed in Figures 10 and 11 or a rail according to Fig. 12 and 13. Two connectors 13 include two clamping members 14 connecting pedicle screws 15 to said rods 12. The rods 12 and rails are made from the same material as the plates 1 and 1' and the filaments encapsulated in the matrix are preferably oriented in axial direction. A rail 17 with a rectangular cross section as shown in Fig. 12 and 13 is more stable to rotation than a rod.

Another advantage of implants manufactured from a carbon filament composite material is that its strength, flexibility and hardness can be varied by changing the ratio of filaments to plastic. It has been found, that "bone growth" is enhanced when it is under a certain degree of physiological stress. Thus, it

will be desirable to select a composite ratio for the plate to gain the required degree of stiffness without sacrifying any strength. The ratio of filaments to plastic is preferably higher than 40% (weight) and more preferably higher than 60% (weight).

The filaments of fibers are not randomly embedded, but oriented in layers A as shown in Fig. A. The layers A can be parallel to each other and to a surface 23 as shown in Fig. 13. The layers A may be made up of woven filaments 18 and 19. The filaments 18 are oriented in the axial direction of the longitudinal implant 1, 17 and 30. The filaments 19 are oriented perpendicular to the axial direction. The filaments 18 and 19 are oriented to resist the biomechanical forces as for example bending force as shown in Fig. 9. The filaments can also be coiled to resist torsion forces. The distance D between two layers A is preferably less than 0.5 mm and preferably about 0.1 mm.

Claims

1. Longitudinal implant and connecting device wherein said longitudinal implant is fastened to bones on either side of a damaged area through that connecting device, said implant is comprised of a filament or fiber composite material and said connecting device is made of a material harder than said longitudinal implant.

2. Connecting device according to claim 1, wherein the longitudinal implant is made of a carbon filament composite material.

3. Connecting device according to claim 1 or 2, wherein the filaments are encapsulated in a polymer matrix.

4. Connecting device according to claim 3, wherein the filaments are encapsulated in PEEK or PEKEKK.

5. Connecting device according to any of claims 1 to 4, wherein the filaments are oriented.

6. Connecting device according to claim 1, wherein the implant being an elongated plate having a longitudinal slot extending along a substantial portion of its length.

7. Connecting device according to claim 6, wherein the connecting device comprising a pedicle screw having an upper section having a width greater than the width of said slot and exteriorly threaded portion extending outwardly from said section and extending through said slot.

8. Connecting device according to claim 7, wherein an interiorally threaded nut is received by the outer end of said threaded portion whereby said plate can be grasped between said upper section and said nut to tightly secure said plate by threading said upper section.

9. Connecting device according to claim 1, wherein said implant is a rod or a rail.

10. Connecting device according to claim 1, wherein said connecting device comprising a screw and a nut which are made of titanium.

11. Connecting device according to claim 1, wherein said implant is a rail (17) having a rectangular cross section.

12. Connecting device according to any one of claims 1 to 11, wherein the filaments are woven.

Abstract

The longitudinal implant is fastened to bones on either side of a damaged area through a connecting device. Said implant is comprised of a filament or fiber composite material and said connecting device is made of a material harder than said longitudinal implant.

The longitudinal implant is preferably made of a carbon filament composite material, wherein the filaments are encapsulated in a polymer matrix.

(Fig. 1, 2)

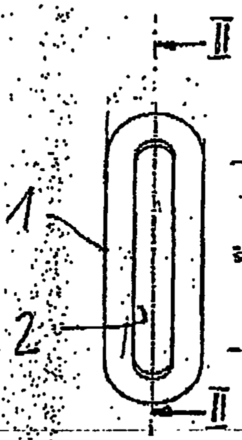

Fig. 1

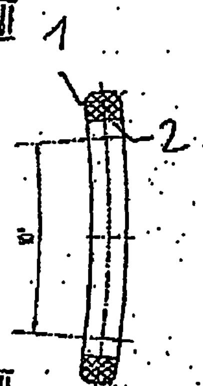

Fig. 2

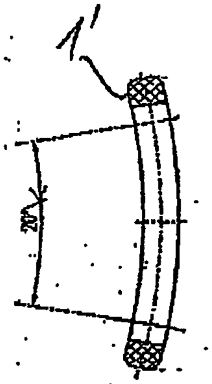

Fig. 3

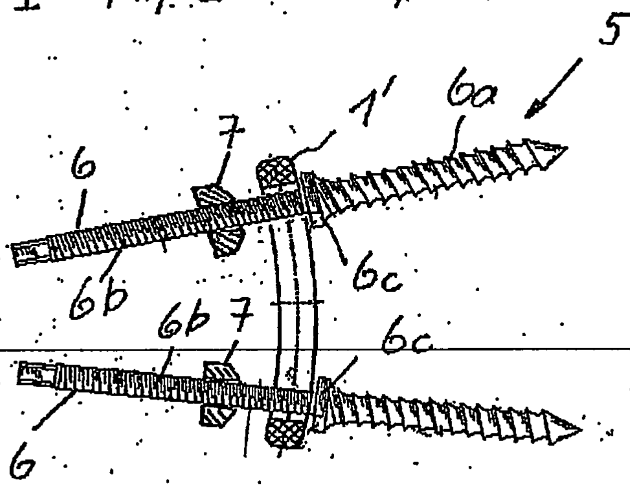

Fig. 4

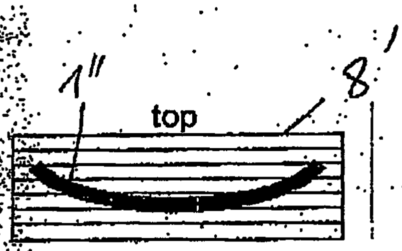

Fig. 5

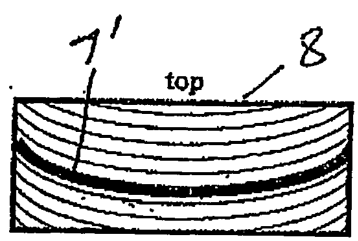

Fig. 6

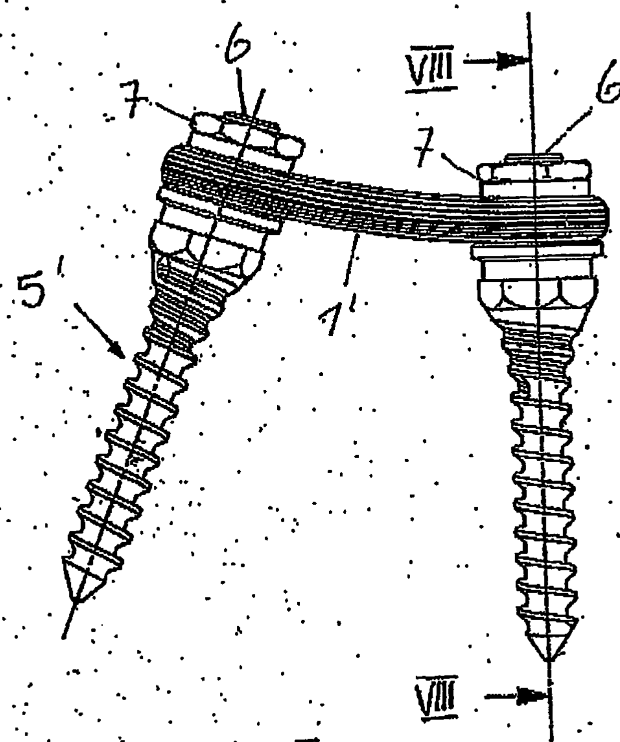

Fig. 7

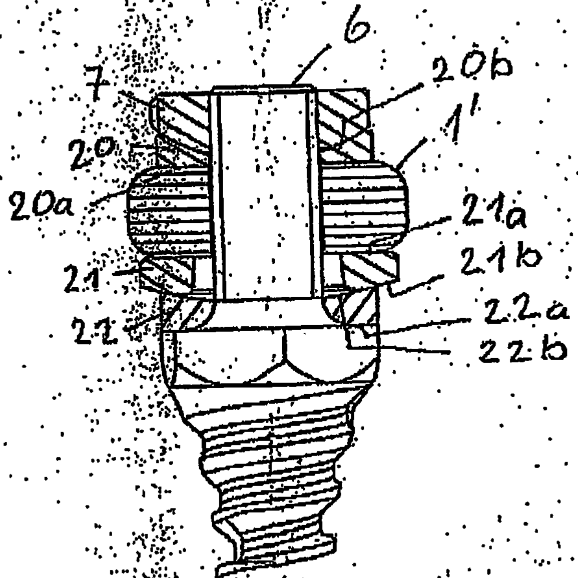

Fig. 8

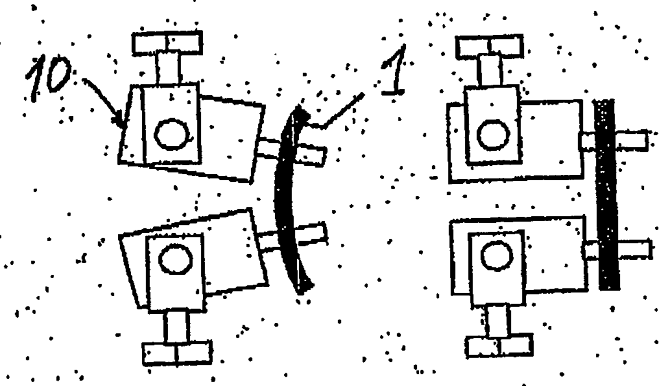

Fig. 9

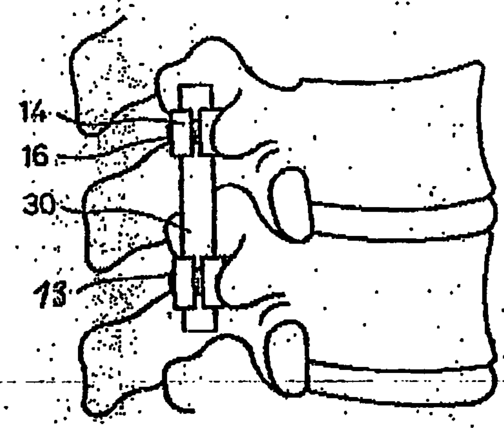

Fig. 10

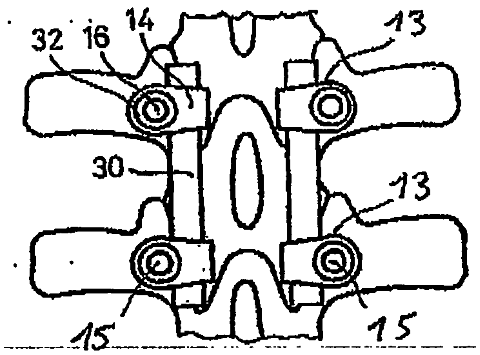

Fig. 11

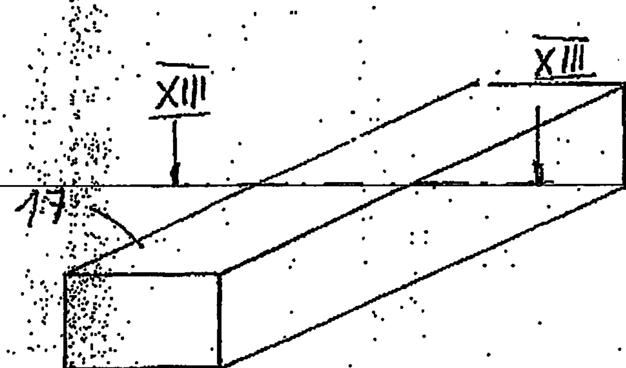

Fig. 1.2

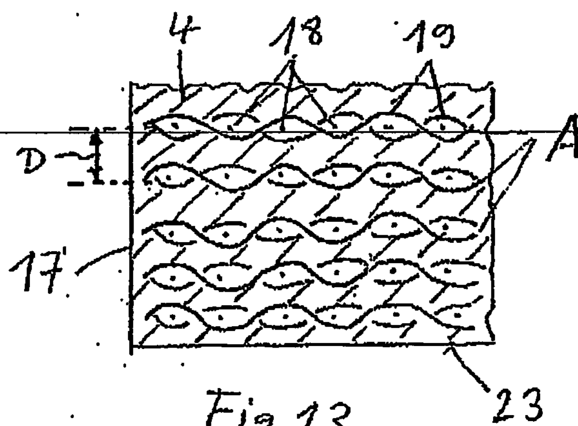

Fig. 13